



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/699,372	10/31/2000	Courtney Hudson	18966.0002	7828

23517 7590 11/02/2004

SWIDLER BERLIN SHEREFF FRIEDMAN, LLP
3000 K STREET, NW
BOX IP
WASHINGTON, DC 20007

EXAMINER

PORTER, RACHEL L

ART UNIT PAPER NUMBER

3626

DATE MAILED: 11/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/699,372

Applicant(s)

HUDSON, COURTNEY

Examiner

Rachel L. Porter

Art Unit

3626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 July 2004 and 09 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/15/2003</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the communication filed 7/7/04 and 8/9/04.
Claims 1-38 are pending. Claims 25-38 are newly added.

Information Disclosure Statement

2. The information disclosure statement filed 1/15/2003, including EP 0936566 A2, has been considered.

Specification

3. The objection to the disclosure for failure to include a brief description of the drawings which indicates that Figure 3 includes several parts is hereby withdrawn due to the response filed 8/9/04.

Claim Rejections - 35 USC § 112

4. The rejection of claim 7 rejected under 35 U.S.C. 112, second paragraph, is hereby withdrawn due to the amendment filed 7/7/04.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 26-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 3626

Claim 26 recites " the method of claim 24..." However, claim 24 recites a computer-readable medium, not a method. It is therefore unclear to the Examiner whether the Applicant intends for claim 26 to be directly dependent from claim 24 or newly added claim 25, which does recite a method. For the purposes of applying art, the Examiner will interpret claim 26 as being dependent from claim 25.

Claim 27 inherits the deficiencies of claim 26 through dependency, and is therefore also rejected.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1-8, 10-14, 17-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Michelson et al (USPAN 2002/0002474).

[claim 1] Michelson teaches a method for matching patients with clinical trials, comprising:

Art Unit: 3626

- receiving patient profile information for a patient at a server connected to a computer network, the patient profile information submitted by a user at a terminal connected to the network, (par. 80,89-94; Figure 2A/2B-6B)
- comparing the patient profile information with acceptance criteria for clinical trials stored in a database, the comparison performed by the server; and (par. 80-83; 105, 166-170; Figure 14)
- determining whether the patient prequalifies for any of the clinical trials; and (par. 113; 166-170; figure 14)
- notifying the user whether the patient has prequalified for any clinical trial. (par. 113; 168-170)

[claim 2] Michelson teaches a method, wherein the steps of comparing, determining, and notifying comprise:

- comparing the patient profile information with acceptance criteria for clinical trial sites stored in a database, the comparison performed by the server; (par. 80-83,105, 166-170; Figure 14)
- determining whether the patient prequalifies for any of the clinical trial sites; and (par. 113; 166-170; figure 14)
- notifying the user whether the patient has prequalified for any clinical trial sites. (par. 113)

[claim 3] Michelson teaches the method of claim 2, further including providing the user with instructions for enrolling in the clinical trial for which the user has prequalified. (par. 162-163, 171)

Art Unit: 3626

[claim 4] Michelson teaches the method of claim 2, further including:

- asking the user a plurality of questions; and (par. 80-83; 162-170)
- creating a patient profile based on the responses to the plurality of questions. (par. 162-163)

[claim 5] Michelson teaches a method wherein the step of asking the user a plurality of questions includes:

- asking the user one or more static questions; (par. 162-163)
- asking the user one or more dynamic questions which are selected based on the user's responses to other static and dynamic questions; and (par. 162-167)
- creating a patient profile based on the responses to the static and dynamic questions. (par. 83, 169)

[claim 6] Michelson teaches the method of claim 3, further including:

- asking the user a series of questions targeted to a specific clinical trial site after determining that a patient meets preliminary acceptance criteria for the specific clinical trial; and (par. 168-169)
- determining whether the user prequalifies for the specific clinical trial based on the user's response to the targeted questions. (par. 168-169)

[claim 7] Michelson teaches the method of claim 6, wherein the static questions, dynamic questions, and targeted questions are provided with a plurality of answer options, and the user may select one or more answer options in order to answer the questions. (figures 4A-4C; par. 83)

Art Unit: 3626

[claim 8] Michelson teaches the method of claim 7, wherein the user is required to submit an answer in a specified format, the specified format being suitable for evaluation by a computer program process. (figures 4A-4C; par. 83)

[claim 10] Michelson teaches the method of claim 1, wherein the network is the Internet. (par. 80-83; 89-91)

[claim 11] Michelson teaches the method of claim 1, wherein the user is provided with an application to submit for a clinical trial for which the patient has prequalified. (par. 167-168)

[claim 12] Michelson teaches the method of claim 11, wherein the application is filled out by the user and submitted on-line to the server. (par. 89-98, 102, and 162-170)

[claim 13] Michelson teaches the method of claim 12, wherein the application is forwarded to the clinical trial site. (par. 165-170)

[claim 14] Michelson teaches the method of claim 13, wherein the patient profile is forwarded to the clinical trial site with the application. (par. 166-170)

[claim 17] Michelson teaches the method of claim 1, wherein the user is provided with a search engine that allows the user to search for medical information before selecting a clinical trial. (par. 92-94)

[claim 18] Michelson teaches the method of claim 1, wherein the acceptance criteria include geographic location. (par. 167)

[claim 19] Michelson teaches a system for matching patients with clinical trials comprising:

Art Unit: 3626

- a server connected to a network; (par. 80; Figures 1A-1B)
- a data storage device included in the server; and (par. 80-83)
- a database located in the data storage device, the database storing patient profile information for a patient and acceptance criteria for a plurality of clinical trials; (par. 80-83)
- the server comparing the patient profile information with the acceptance criteria for the clinical trials stored in the database, determining whether the patient prequalifies for any of the clinical trials, and notifying a user whether the patient has prequalified for any clinical trials. (par. 80-83; par. 113)

[claim 20] Michelson teaches system of claim 19, wherein the database contains at least one of: a) disease/sub-disease records; b) drug records; c) content records; d) clinical trial records; e) question records; f) device records; g) patient profile records; h) user registration records; and i) trial site records. (par. 82-84; 87-88)

[claim 21] Michelson teaches the system of claim 20, wherein a record in the database contains links to other related records. (par. 88)

[claim 22] Michelson teaches the system of claim 20, wherein the server transmits a plurality of questions to the user over the network, the server also transmits a plurality of answer choices for each question, the server receives responses from the user, and the server builds a patient profile based on the responses. (par. 80-83, 87)

[claim 23] Michelson teaches a system wherein the server retrieves a disease/sub-disease record corresponding to a disease/sub-disease entered by the user, the

Art Unit: 3626

disease/sub-disease record containing links to question records, the server retrieving the question records to access questions to be provided to the user. (par. 80, 82-83, 87)

[claim 24] Michelson teaches computer executable software code stored on a computer readable medium, performing a method for matching patients with clinical trials, comprising:

- receiving patient profile information for a patient at a server connected to a computer network, the patient profile information submitted by a user at a terminal connected to the network; (par. 80, 89-94; Figure 2A/2B-6B)
- comparing the patient profile information with acceptance criteria for clinical trials stored in a database, the comparison performed by the server; and (par. 80-83; 105, 166-170; Figure 14)
- determining whether the patient prequalifies for any of the clinical trials; (par. 113; 166-170; figure 14) and
- notifying the user whether the patient has prequalified for any clinical trials. (par. 113; 168-170)

9. Claims 25-38 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Michelson et al (USPAN 2002/0002474).

Insofar as the newly added claims were copied from the Michelson reference, it is submitted that these claim limitations are clearly anticipated by the Michelson publication.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Michelson in view of Altman et al (USPN 5,572,421).

[claim 9] Michelson teaches the method of claim 8 as explained in the rejection of claim 8, but does not expressly disclose that the questions asked of the user are updated.

Altman discloses a method wherein patient question are updated periodically. (col. 9, lines 42-48) At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method of Michelson with the teaching of Altman to periodically update the patient questions. As suggested by Altman, one would have been motivated to include this feature to keep up the progress of medical knowledge.

(Altman: col. 4, lines 19-22)

12. Claims 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michelson in view of Kraftson et al (USPN 6,151,581).

[claim 15] Michelson teaches a method for matching patients with clinical trials as explained in the rejection of claim 14. Michelson further discloses storing patient profiles (par. 98, 190-191) and wherein patient privacy is guarded (par. 30), but does

Art Unit: 3626

not expressly disclose that the patient record and application include a patient ID to conceal the patient's identity. Kraftson teaches a system/method wherein a random ID number is assigned to a patient's profile and questionnaire to conceal/protect the patient's identity. (col. 12, lines 53-62) At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method of Michelson with the teaching of Kraftson to store the patient's information with a patient ID number. As suggested by Kraftson, one would have been motivated to include this feature to ensure that the patient is free to answer questions honestly and accurately with fear that his/her information will be divulged. (col. 12, lines 35-49)

[claim 16] Michelson teaches a method further including notifying the clinical trial sponsor when the user submits an application to the clinical trial site. (par. 108-112)

Response to Amendment

(A) It is noted that the Applicant has attempted to declare an interference between the present application (09/699,372) and the Michelson et al application USAP 2002/0002474A1 (09/923,385), has also been cited as prior art in rejection of claims 1-38 in the application. In accordance MPEP §2303:

[w]here two or more applications are found to be claiming the same *patentable* invention, they may be put in interference, dependent on the status of the respective applications and the difference between their filing dates. One of the applications should be in condition for allowance. (*emphasis added*)

It should be noted that none of the claims in recited in and copied from the Michelson et al published application have not been indicated as allowable or patentable. Likewise, none of the claims in the present application have been indicated as allowable or

Art Unit: 3626

patentable. Therefore, neither of the applications is in condition for allowance and, the two applications are not subject to interference at this time.

(B) Insofar as applicant has not presented any additional arguments regarding claims 1-24, the rejection of the claims has been maintained. New grounds of rejection have been provided to address the newly added claims 25-38.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- Machlis ("Web Links Cancer Patients to Drug Trials") discloses a web-implemented system for physicians and patients to find out about new drug trials.
- www.centerwatch.com (archived Dec. 1998) discloses method for recruiting a person to participate as a subject in a clinical study.
- "Pharmaceutical industry Embraces Clinmark Dotcom" discloses a system for providing electronic bulletin boards to exchange information regarding clinical studies.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

Art Unit: 3626

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel L. Porter whose telephone number is 703-305-0108. The examiner can normally be reached on M-F, 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (703)305-9588. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



ALEXANDER KALINOWSKI
PRIMARY EXAMINER

RP
RP